DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

m36190

January 12, 1999

WARNING LETTER
CHI-7-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bernard C. Robertson, Co-Owner
Robertson Farm
6187 Cherry Valley Road
Kirkland, IL 60146

Dear Mr. Robertson:

An investigation of your cattle raising operation, conducted by Thomas W. Nojek on November 13 and 17, 1998, found that you offered a cow for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) and Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act).

On or about September 9, 1998, you sold a cow to [redacted] which was subsequently shipped for slaughter as human food [redacted] analysis of tissue samples collected from that animal identified the presence of 63.00 parts per million (ppm) penicillin in the kidney tissue and 00.59 ppm penicillin in the liver tissue. The established regulatory action level for penicillin in cattle is 0.05 ppm. The presence of this drug in the edible tissue from this animal causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act.

Investigator Nojek's investigation further revealed that the drugs used to treat the subject animal were not administered in the manner recommended in the products' label directions for use. You have also failed to maintain records covering the treatment of your animals with drug products which require withdrawal times. The failure to follow label directions and institute a system whereby medicated animals can be identified and traced, causes the food (meat) to be adulterated under section 402(a)(4) of the Act in that the food was prepared, packed or held under conditions whereby it may have become contaminated.

The above is not intended as an all-inclusive list of violations. A List of Observations (form FDA 483) was issued to you at the conclusion of the inspection. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes official notification under the law.

Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Paul A. Boehmer, Compliance Officer.

Sincerely,

/s/
Raymond V. Mlecko
District Director

Enclosure: form FDA 483

cc: Manzoor Chaudry, DVM
Branch Chief, Residue Staff
Food Safety and Inspection Service
U.S. Dept. of Agriculture
Technical Service Center
106 S. 15th St., Ste 904
Omaha, NE 68102

cc: Richard Hull, DVM
Chief Veterinarian
Bureau of Animal Health
Division of Animal Industries
Illinois Department of Agriculture
P.O. Box 19281
Springfield, IL 62794-9281

cc: Mark Ringler
Bureau Manager
Bureau of Agricultural Products Inspection
Division of Agricultural Industry Regulations (DAIR)
Illinois Department of Agriculture
Post Office Box 19281
Springfield, IL 62794-9281